



1101 30th Street NW, Suite 200  
Washington, DC 20007  
(202) 534-1440 | [www.CandyUSA.com](http://www.CandyUSA.com)

August 29, 2018

Via <https://oehha.ca.gov/comments> and email to [Monet.Vela@OEHHA.ca.gov](mailto:Monet.Vela@OEHHA.ca.gov)

Monet Vela  
Regulations Coordinator  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010  
Sacramento, CA 95812-4010

Re: **Proposed Rulemaking by OEHHA regarding a Potential Section 25704 of the Proposition 65 Regulations**

I am writing on behalf of the National Confectioners Association (NCA) and its member companies with respect to the Office of Environmental Health Hazard Assessment's (OEHHA's) request for public comment concerning the potential adoption of a new section 25704 of the Proposition 65 regulations establishing that exposures to listed chemicals in coffee pose no significant risk within the meaning of the statute.

**Summary.** NCA requests that OEHHA re-organize its proposal such that, while applying immediately to coffee in the manner proposed, section 25704 of the Proposition 65 regulations may potentially be used in the future to establish further subsections that would extend its application to other foods and/or to levels of specified chemicals in other foods, so that they too can be deemed to pose no significant risk. (See Attachment.)

**Background.** NCA is the trade organization that advances, protects, and promotes chocolate, candy, gum and mints, and the companies that make these special treats. As the leading association for the \$44.6 billion U.S. confectionery industry, NCA educates the public to help ensure that people understand and appreciate the unique role that chocolate and candy can play in a happy, balanced lifestyle. The majority of our manufacturing member companies are small and medium-sized. Chocolate and candy are produced in all 50 states, employing approximately 54,000 workers in nearly 1,300 manufacturing facilities across the country. More than 550,000 Americans working in agriculture, retail, transportation, and other industries rely in part on the sale of confections for their livelihood. In fact, for every one job that America's chocolate and candy companies create in manufacturing, another ten are supported in related industries. Nearly 200 confectionery manufacturers are based in and/or have facilities and operations in California.

In both the past and the present, NCA member companies and their customers have been subjected to bounty hunter claims initiated by a variety of Proposition 65 plaintiffs. These claims have typically included allegations that the confectionery product in question requires a warning label under Proposition 65. Some of these actions have been accompanied with public relations campaigns that are designed to provoke media attention and scare consumers, including with suggestions that the ordinary consumption of safe and enjoyable confectionary may result in cancer.

NCA member companies often cannot afford to litigate Proposition 65 claims based on establishing a no significant risk defense in contested litigation because of the time and costs involved. Nor do many of them have the resources necessary to counteract public relations and other scare tactics even where the allegations about cancer arising from the consumption of their products are not based in science. Even potential regulatory processes, such as safe use determinations, are not a viable option for those concerned. These burdensome efforts should not be necessary where evidence of carcinogenicity from the consumption of the products in question has not been established and they have more generally been recognized as safe by food regulators here in the United States and abroad.

#### *Comments.*

1. **OEHHA should proceed to deem that chemicals in coffee pose no significant risk under Proposition 65.** The proposed trial court decision in the longstanding Proposition 65 acrylamide in coffee litigation reads both science and common sense out of the statute and threatens its continuing viability. If its reasoning were allowed to stand, other cases would follow on the same basis and the credibility of Proposition 65 and warnings for cancer risks that truly are significant would be severely undermined. As OEHHHA's Initial Statement of Reasons (ISOR) documents, there is ample scientific evidence that coffee does not increase the risk of cancer regardless of the particular chemicals it contains and that, beyond this, coffee also contains antioxidants and other compounds that reduce the risk of certain cancers and provide other beneficial health effects. The rationale and basis for OEHHHA's proposed regulation with respect to coffee is therefore compelling and the agency should proceed to finalize its decision in that regard with all deliberate speed.
2. **OEHHA should not create a de facto standard that IARC must make a specific finding that a food does not pose a risk of cancer in humans in order for it to be deemed to pose no significant risk for purposes of Proposition 65.** NCA agrees with the ISOR to the extent it observes that the preponderance of evidence on the lack of carcinogenicity of coffee to humans and its potential cancer suppression and other health effects is unique and unparalleled. But it would be unrealistic and well beyond what the statute requires for OEHHHA to set the bar that high with respect to the potential need to consider, in the future, whether other foods should be deemed to pose no significant risk for purposes of Proposition 65. In this regard, OEHHHA

should clarify in its final statement of reasons that, while relevant with respect to the proposed regulation on coffee, action by IARC determining a lack of carcinogenicity of a food is not a necessary prerequisite with respect to OEHHA taking similar actions concerning other foods in the future and that the agency will instead continue to itself evaluate the weight of scientific evidence in making such determinations.<sup>1</sup>

3. **In the future, OEHHA should also use section 25704 to promulgate alternative no significant risk levels for listed carcinogens in foods that arise from roasting/cooking.** The State has long recognized in section 25703(b)(1) of the Proposition 65 regulations that “sound considerations of public health” may justify acceptance of a cancer risk level for a listed chemical that deviates from the default level the statute would otherwise impose. However, as the decision in the coffee matter underscores, ambiguities in that regulation make its application in the context of contested litigation impractical if not impossible and trial courts are not necessarily well-equipped to consider the scientific and public policy tradeoff issues involved.

Accordingly, where credible scientific evidence demonstrates that a food presents other health benefits, even if sufficient evidence does not yet exist to demonstrate that it will not cause cancer in humans, to give practical effect to it prior regulation, OEHHA should in the future use subsections of section 25704 to adopt specific alternative no significant risk levels for listed chemicals that arise in those foods as the result of roasting or cooking undertaken to render them safe or palatable.

**Conclusion:** California consumers have and continue to periodically enjoy a wide variety of NCA member companies’ confectionery products. These products do not contain chemicals at levels that would render them carcinogenic or unsafe. Some confectionery products, notably cocoa and chocolate, contain flavanols, which have been demonstrated to have important contributions to the diet.<sup>2 3</sup> In fact, cocoa flavanol intake is currently actively being studied for the potential impact on cancer endpoints.<sup>4</sup>

---

<sup>1</sup> NCA reads the ISOR (p. 6) to state that OEHHA’s proposed regulation concerning coffee is ultimately based on “moderate or strong evidence that coffee either reduces risk or does not affect risk of cancers” that account for those most commonly diagnosed in women and men in California respectively. This is a legally and scientifically appropriate and pragmatic basis upon which to reach no significant risk determinations under Proposition 65 for widely consumed foods.

<sup>2</sup> Consumption of confectionary has previously been associated with greater longevity. Lee I-M, Paffenbarger RS. Life is sweet: candy consumption and longevity. *BMJ*: 1998;317(7174):1683-1684. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC28747>.

<sup>3</sup> A substantial body of evidence has evaluated the impact of cocoa flavanols on cardiovascular disease endpoints Hooper L, Kay C, Abdelhamid L, et al. Effects of chocolate, cocoa, and flavan-3-ols on cardiovascular health: a systematic review and meta-analysis of randomized trials. *AJCN*, 2012; 95 (3): 740–751. <https://academic.oup.com/ajcn/article/95/3/740/4576702>.

<sup>4</sup> Currently, data collection by researchers based at the Brigham and Women’s Hospital, an affiliate of the Harvard Medical School, is nearing completion in association with a major multi-year study involving approximately 22,000 men and women across the United States concerning, among other things, the potential anti-carcinogenic effects of cocoa flavanols. <https://www.cosmostrial.org/index.html>.

Thus, in addition to adopting its proposal for coffee in an appropriate initial subsection, NCA urges OEHHA to structure proposed section 25704 to enable future rulemakings that would allow other foods to come within its scope. (See Attachment.)

We very much appreciate the opportunity to offer our views and comments on this issue.

Sincerely,

Laura Shumow  
Vice President, Scientific and Regulatory Affairs  
National Confectioners Association

ATTACHMENT  
(Suggested Re-Casting of Proposed Section 25704)

**TITLE 27. ENVIRONMENTAL PROTECTION**

**DIVISION 4. OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**CHAPTER 1. SAFE DRINKING WATER  
AND TOXIC ENFORCEMENT ACT OF  
1986**

**ARTICLE 7. NO SIGNIFICANT RISK LEVELS**

**§ 25704. Exposures to Listed Chemicals in-Coffee Food Posing No Significant Risk**

(a) Exposures to listed chemicals in coffee created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer.

(b) [Reserved for future comprehensive no significant risk determinations as to other foods]

(c) [Reserved for future alternative no significant risk levels for specific chemicals arising due to roasting or cooking of foods having other important contributions to the diet]

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.10, Health and Safety Code.